DEVICE AND A METHOD FOR TREATMENT OF ATRIOVENTRICULAR REGURGITATION

BACKGROUND OF THE INVENTION

The invention relates to a device for treatment of atrioventricular regurgitation and a method for treatment of atrioventricular regurgitation using said device.

The heart has two atrioventricular valves, the mitral valve, which is situated between the left atrium and the left ventricle, and the tricuspid valve situated between the right atrium and the right ventricle. The tricuspid valve has three leaflets, two of which are much bigger than the third. These two bigger leaflets could be considered to correspond to the two leaflets of the mitral valve. Therefore, only the mitral valve will hereinafter be discussed although corresponding discussions could apply to the tricuspid valve.

Mitral regurgitation is the medical name of a problem that occurs in the heart. A person that suffers from mitral regurgitation has a mitral insufficiency, i.e. the mitral valve between the left atrium and the left ventricle cannot close entirely. Thus, when the ventricle is contracted in order to pump out blood through the aorta, some blood leaks back into the atrium instead. This will lead to a reduced functionality of the left ventricle and subsequently to heart insufficiency, which is a mortal disease.

Mitral insufficiency can result from, for example, ischemic disease, degenerative disease of the mitral apparatus, rheumatic fever, endocarditis, congenital heart disease and cardiomyopathy. The four major structural components of the mitral valve are the annulus, the two leaflets, the chordae and the papillary muscles. Any one or all of these in different combinations may be injured and create insufficiency.

At present mitral regurgitation is treated by open-heart surgery. This is a major operation and requires the use of total cardiopulmonary by-pass, aortic cross clamping and cardioplegic arrest. To certain groups of patients this is particularly hazardous and there is an apparent risk of not surviving the operation.

The treatment consists of either mitral valve replacement or repair. Replacement can be performed with either mechanical or biological valves.

The mechanical valve carries the risk of thromboembolism and requires anticoagulation, with all its potential hazards, whereas biological prostheses suffer from limited durability. Another hazard in connection with replacement is the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

The four basic techniques of repair include the use fan annuloplasty ring, quadrangular segmental resection of diseased posterior leaflet, shortening of elongated chordae, and transposition of posterior leaflet chordae to the anterior leaflet. The techniques of mitral valve repair rely on decreasing valve area to increase leaflet apposition, but fail to address subvalvular dysfunction. Mitral insufficiency caused by prolapse of the anterior leaflet, posterior leaflet with calcified annulus, or prolapse of both leaflets constitutes a more demanding challenge to repair.

In 1995 Alfieri et al introduced modifications in the operative technique that allow a more expeditious and reproducible procedure than the traditional of greater complexity. This is achieved by simply anchoring the prolapsing free edge of the leaflet to the facing edge of the other leaflet (edge-to-edge technique), thus creating a double orifice of the mitral valve. The hemodynamic behavior of a double orifice mitral valve does not differ from that of a physiological valve of the same total area. Pressure drops and flow velocity across the valve are not influenced by the configuration of the valve.

Some efficient methods of treating mitral insufficiency exist as shown above, but all of them require open-heart surgery. Since many patients with mitral regurgitation are elderly or have a poor left ventricular function, they would benefit from a less invasive procedure that does not involve the use of cardiopulmonary by-pass as required by conventional techniques.

SUMMARY OF THE INVENTION

The object of the invention is to provide a device and a method for treatment of atrioventricular regurgitation that will be applicable to a beating heart.

This is accomplished by a device according to claim **1** and a method according to claim **14**. Preferred embodiments of the device and the method are defined in the dependent claims **2–14**, respectively.

Thus, a device for treatment of atrioventricular regurgitation comprises a suturing means having such dimensions as to be introducible, via blood vessels leading to the heart, to two leaflets of an atrioventricular valve between an atrium and a corresponding ventricle of the heart and being designed for binding together the two leaflets in a position along the free edges of the leaflets, whereby the closing of the atrioventricular valve is improved.

Preferably, the atrioventricular valve is the mitral valve between the left atrium and the left ventricle of the heart.

Diseases to the atrioventricular valves are much more common in the mitral valve than in the tricuspid valve. Therefore the focus of the invention is on the treatment of the mitral valve although treatment of the tricuspid valve could work equally well using the device.

The suturing means is preferably transitional between two states, being open in a first state and substantially closed in a second state.

This makes the suturing means capable of reaching the free edges of the mitral leaflets in the first state and of bringing them closer to each other when transitioned into the second state.

In a preferred embodiment, the suturing means comprises a clip.

Preferably, the clip has two arms pivotally connected to each other at a first end thereof, the arms forming a V in the first state of the clip and being substantially parallel in the second state of the clip.

Consequently, the arms of the clip can capture both mitral leaflets in the first state and bring them closer together in the second state.

Desirably, the arms of the clip have second, free ends bent towards each other so that these ends of the arms in the second state of the clip are brought proximal to each other.

This means that the mitral leaflets can be brought in close proximity to create a suture as the ends of the arms capturing the mitral leaflets in the second state of the clip are brought proximal to each other.

Further, each second end of the arms is preferably sharp.

As a result, the clip can easily capture the mitral leaflets and are capable of gripping the leaflets between its arms.

Suitably, the clip has two pairs of arms connected to each other by two crossbars near the connected first ends of the arms.